

CLAIMS

The following listing of claims will replace all previous versions of claims presented in this application:

1. (Original) A biodegradable neurotoxin implant, comprising: a neurotoxin component associated with; a biodegradable polymer component; and an acidity regulating component for establishing in vivo a pH in the vicinity of the neurotoxin component associated with the implant of less than about 7.
2. (Original) The implant of claim 1, wherein the neurotoxin component comprises a Clostridial neurotoxin.
3. (Original) The implant of claim 1, wherein the neurotoxin component comprises a botulinum toxin.
4. (Original) The implant of claim 1, wherein the neurotoxin component comprises a botulinum toxin selected from the group consisting of botulinum toxin types A, B, C₁, D, E, F, and G, and mixtures thereof.
5. (Original) The implant of claim 1, wherein the implant comprises an amount of a botulinum toxin between about 1 unit and about 500,000 units.
6. (Original) The implant of claim 1, wherein the implant comprises an amount of a botulinum toxin type A between about 10 units and about 2000 units.
7. (Original) The implant of claim 1, wherein the biodegradable polymer component is effective in controlling release of the neurotoxin from the implant when the implant is located in a patient's body

8. (Original) The implant of claim 1, wherein the biodegradable polymer component includes a polymer selected from the group consisting of polyesters, poly(ortho esters), and polyanhydrides, and mixtures thereof.

9. (Original) The implant of claim 1, wherein the biodegradable polymer component comprises at least one polymer selected from the group consisting of poly-lactic acid (PLA), poly (lactide-co-glycolide) acid (PLGA), poly-L-lactic acid (PLLA), polycaprolactone, and poly (ortho acetate), and mixtures thereof.

10. (Original) The implant of claim 1, wherein the biodegradable polymer component includes a polymer that includes at least one ester bond, and biodegradation of the polymer occurs by hydrolysis of the at least one ester bond.

11. (Original) The implant of claim 1, wherein the acidity regulating component is provided in an amount effective in maintaining a pH of the implant to a value less than about 7 when the implant is located in a patient's body

12. (Original) The implant of claim 1, wherein the acidity regulating component is effective in maintaining the pH of the implant in a range of about 3 to about 7.

13. (Original) The implant of claim 1, wherein the acidity regulating component is effective in maintaining the pH of the implant in a range of about 4 to about 6.

14. (Original) The implant of claim 1, wherein the acidity regulating component is effective in stabilizing the neurotoxin as the implant biodegrades.

15. (Original) The implant of claim 1, wherein the acidity regulating component is effective in maintaining the neurotoxin in a stabilized form during the life of the implant.

16. (Currently amended) The implant of claim 1, wherein the acidity regulating component comprises a (i) ~~a monomer from which a biodegradable polymer is derived, and~~ (ii) ~~an oligomer including monomeric units substantially identical to monomeric units included in the biodegradable polymer~~ a monomer and an oligomer derived from the same biodegradable polymer.

17. (Original) The implant of claim 16, wherein the monomers and oligomers are provided in a range of about 0.1% (w/w) to about 30% (w/w) of the implant.

18. (Currently amended) The implant of claim 1, wherein the acidity regulating component comprises a combination of ~~monomers from which a biodegradable polymer is derived and oligomers including monomeric units substantially identical to monomeric units included in the biodegradable polymer~~ monomers and oligomers derived from the same biodegradable polymer.

19. (Original) The implant of claim 17, wherein the biodegradable polymer is selected from the group consisting of polyesters, poly (ortho esters), polyanhydrides, and mixtures thereof.

20. (Original) The implant of claim 17, wherein the biodegradable polymer is selected from the group consisting of poly-lactic acid (PLA), poly (lactide-co-glycolide) acid (PLGA), poly-L-lactic acid (PLLA), polycaprolactone, poly (ortho acetate), and mixtures thereof.

21. (Currently amended) The implant of claim 1, wherein the biodegradable polymer component includes a first biodegradable polymer, and the acidity regulating component includes ~~at least one of (i) monomers from which the first biodegradable polymer is derived, and (ii) oligomers including monomeric units substantially~~

~~identical to monomeric units included in the first biodegradable polymer~~ includes a monomer and an oligomer derived from the first biodegradable polymer.

22. (Canceled).

23. (Original) The implant of claim 1, wherein the biodegradable polymer component includes a first biodegradable polymer, and the acidity regulating component ~~includes at least one of (i) monomers from which a second biodegradable polymer is derived, and (ii) oligomers including monomeric units substantially identical to monomeric units included in a third biodegradable polymer~~ includes a monomer and an oligomer derived from the same second biodegradable polymer.

24. (Original) The implant of claim 1, further comprising a pharmaceutically acceptable excipient.

25. (Original) The implant of claim 1, wherein the acidity regulating component comprises monomers from which a biodegradable polymer is derived, and the implant further comprises salts of the monomers.

26. (Currently amended) A biodegradable neurotoxin implant, comprising: a neurotoxin component; a biodegradable polymer component; and an acidity regulating component including ~~at least one of (i) monomers from which a biodegradable polymer is derived and (ii) oligomers including monomeric units substantially identical to monomers from which a biodegradable polymer is derived~~ including a monomer and an oligomer derived from the same biodegradable polymer.

27. (Original) The implant of claim 26, wherein the neurotoxin component comprises a botulinum toxin type A.

28. (Canceled).

29. (Original) The implant of claim 26, wherein the acidity regulating component includes at least one of (i) a first monomer and (ii) an oligomer derived from a second monomer different from the first monomer, and the biodegradable polymer is derived from a third monomer different from both the first and second monomers.

30. (Currently amended) A biodegradable neurotoxin implant, comprising: a neurotoxin component comprising a botulinum toxin type A; a biodegradable polymer component including at least one biodegradable polymer effective in regulating the release of the botulinum toxin type A from the implant; and an acidity regulating component including ~~(i) monomers from which a biodegradable polymer is derived, and (ii) oligomers including monomeric units substantially identical to the monomers~~ a monomer and an oligomer derived from the same biodegradable polymer.

31. (Original) The implant of claim 30, wherein the biodegradable polymer component includes a plurality of different biodegradable polymers.

32. (Original) The implant of claim 30, wherein the acidity regulating component includes monomers from which a biodegradable polymer of the biodegradable polymer component is derived.

33. (Original) A method of making the implant of claim 30, comprising a step of blending the neurotoxin component, the biodegradable polymer component, and the acidity regulating component together.